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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,227	04/20/1998	JESUS W. CASAS-BEJAR	P-7109	4100

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EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/063,227

Applicant(s)

SCHROEDER ET AL.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-19, 24, 27, 29, 33, 34, 36-39, 41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-19, 24, 27, 29, 33, 34, 36-39, 41, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al (US 5,447,724).

Helmus teaches all the claimed subject matter including an implantable medical device (col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46), wherein the drug makes up 2% by weight of the material (col. 7, lines 57-62).

Note that col. 7, lines 57-62 indeed specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col.

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6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724).

Helmus teaches all the claimed subject matter except for the slightly lower concentrations in claims 37 and 43. Helmus teaches 2% of the material is the drug, whereas the claims call for a maximum of 1%. In a tissue-contacting wall of a catheter, the amounts of a drug that are needed to achieve a desired release rate vary somewhat based on the specific material that the drug is being mixed into, and also how the catheter was formed (i.e. extrusion process, etc.). Therefore, the examiner takes the position that it would have been obvious to one of ordinary skill in the art to vary the weight percentage of a drug such a small amount in order to achieve a desired release rate depending on the polymer being used and the manufacturing process (temperature, curing, etc) used to make the catheter.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chait (US 5,727,555) in view of Helmus et al (US 5,447,724).

Chait teaches a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. However, Chait lacks a layer with anti-inflammatory agent in it. Helmus teaches an elongate body-inserted member with an anti-inflammatory agent imbedded in the tissue-contacting surface as discussed supra. It would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Helmus in order to reduce inflammation in the treatment area, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Claims 17-19, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629).

Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot teaches the use of dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

### ***Response to Arguments***

Applicant's arguments filed 11 March 2002 have been fully considered but they are not persuasive.

Applicant argued that Helmus does not teach a tissue-contacting layer with a drug intimately mixed in it. Applicant cited figures 1b and 1c, and referred to agent-containing layer 23. However, as clarified by the discussion above, Helmus does in fact teach a steroid in the outer layer.

Applicant argued that the steroids in Chait are "anti-proliferative" rather than "anti-inflammatory" (the examiner interprets this argument to be drawn to Helmus since Chait was not used for any teaching of steroids). Closely reading column 6, lines 54-55 of Helmus, which read..."anti-proliferative agents such as heparin AND steroids such as **cortisone**". These are two separate groups of agents separated by the "AND".

The examiner has provided the entries from Stedman's medical Dictionary for Cortisone and Glucocorticoid to demonstrate that Helmus teaches an "anti-inflammatory" steroid.

### **Stedman's Medical Dictionary 27th Edition**

#### **cortisone**

A glucocorticoid not normally secreted in significant quantities by the human adrenal cortex. Endogenously, it is probably a metabolite of hydrocortisone but exhibits no biological activity until converted to hydrocortisone (cortisol); it acts upon carbohydrate metabolism and influences the nutrition and growth of connective (collagenous) tissues. It was the first glucocorticoid available for therapy. SYN: Wintersteiner compound F.

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**glucocorticoid**

1. Any steroid-like compound capable of significantly influencing intermediary metabolism such as promotion of hepatic glycogen deposition, and of exerting a clinically useful **anti-inflammatory effect**. Cortisol (hydrocortisone) is the most potent of the naturally occurring g. most semisynthetic g. are cortisol derivatives. 2. Denoting this type of biologic activity. SYN: glucocorticoid.

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**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt  
May 30, 2002

ANHTUAN T. NGUYEN  
PRIMARY EXAMINER

A/SP 5/31/02